




**Regulating farm animal cloning
recommendations from the project Cloning in Public**

Gamborg, Christian; Gjerris, Mickey; Gunning, Jennifer; Hartlev, Mette; Meyer, Gitte; Sandøe, Peter; Tveit, Geir

Publication date:
2006

Document version
Publisher's PDF, also known as Version of record

Citation for published version (APA):
Gamborg, C., Gjerris, M., Gunning, J., Hartlev, M., Meyer, G., Sandøe, P., & Tveit, G. (2006). *Regulating farm animal cloning: recommendations from the project Cloning in Public*. Danish Centre for Bioethics and Risk Assessment. Project Report / Danish Centre for Bioethics and Risk Assessment No. 15



PROJECT REPORT

REGULATING FARM ANIMAL CLONING

Recommendations from the project *Cloning in Public*

Christian Gamborg, Mickey Gjerris,
Jennifer Gunning, Mette Hartlev,
Gitte Meyer, Peter Sandøe, Geir Tveit



REGULATING FARM ANIMAL CLONING

Recommendations from the project *Cloning in Public*

Christian Gamborg, Mickey Gjerris,
Jennifer Gunning, Mette Hartlev,
Gitte Meyer, Peter Sandøe, Geir Tveit



DANISH CENTRE FOR BIOETHICS AND RISK ASSESSMENT

REGULATING FARM ANIMAL CLONING

Recommendations from the project *Cloning in Public*

Christian Gamborg, Mickey Gjerris, Jennifer Gunning,
Mette Hartlev, Gitte Meyer, Peter Sandøe, Geir Tveit

*The present report is the last of seven from the project
Cloning in Public – a Specific Support Action within
the 6th Framework Programme of the European Commission,
Priority 5, Food quality and safety (Contract no. 514059).
The project's full title is: Farm animal cloning and the public
– A project to facilitate a European public debate and to make
recommendations on regulation and on guidelines for research
and applications of farm animal cloning.*

***The authors carry the full responsibility of the content of this report.
It does not represent the opinion of the European Commission.***

© Danish Centre for Bioethics and Risk Assessment
and the authors 2006
Project report 15
Report editors: Geir Tveit & Peter Sandøe
Graphic design: Oktan, Peter Waldorph

Danish Centre for Bioethics and Risk Assessment
Rolighedsvej 25
DK - 1958 Frederiksberg C
bioethics@kvl.dk
www.bioethics.kvl.dk

CONTENTS

- 1. **Summary / 7**
- 2. **The report and the project / 9**
- 3. **Applications and regulation / 11**
 - 3.1 Possible developments and regulatory options / 11
 - 3.2 Regulatory options / 12
 - 3.3 Possible development 1: Basic research and biomedicine applications in and outside the EU / 14
 - 3.4 Possible development 2: Basic research and biomedicine applications in and outside the EU, and agricultural applications outside EU / 14
 - 3.5 Possible development 3: Basic research, biomedicine and agricultural applications in and outside the EU / 16
 - 3.6 Assessing regulatory options / 17

1. SUMMARY

The developments in new approaches and techniques in the animal cloning science led in 2004 to the establishment of the project *Cloning in Public*. Two interrelated aims were assigned to the project. One was to provide the EU Commission and other interested parties with recommendations on regulatory issues relating specifically to the cloning of farm animal species. The other was to stimulate public debate on the subject. The present document is the project's final report. It sums up the recommendations with regard to regulatory options.

It is the overall conclusion of the project that the EU would be left with difficult processes of decision-making if the cloning of farm animals were to take place in agricultural production in countries outside (likely) or within (at present unlikely) the EU. Whether a decision is made to rely on existing regulation or to introduce new, specifically targeted legislation, concerns about both free trade and social acceptability in Europe will have to be negotiated.

Three main areas of application have been identified. First, cloning techniques are already in use in basic research, i.e. research aimed at the acquisition of new knowledge about fundamental, biological mechanisms. Second, cloning techniques are also being used in biomedicine to develop new medicines and treatments. Third, cloning may in future be used for agricultural purposes – that is, in the production of meat and dairy products – with the aim of making agricultural production more efficient. The first two of these areas of application represent developments that are either already taking place or in the offing on a global scale. The third area of application is controversial. It represents for the time being a possible development that may take place in some parts of the world but not in others – a development, then, that may give rise to international conflicts over trade. Specifically, there are indications that cloning techniques may be put to use in agricultural production in the USA

but not in the EU. This challenging eventuality must be squarely faced by those considering the regulatory options in the EU.

At present, there is no specific regulation on the cloning of farm animal species in the EU. Thus, at European level animal cloning is now governed only by a rather complex, indirect regulatory patchwork, incorporating general controls on, for instance, the treatment of experimental animals in research, the treatment of production animals in agriculture, and the protection of human health and the free choice of consumers. Much the same is true in individual member states. Only one country, Denmark, has added specific legislation on animal cloning. When considering whether this is a satisfactory state of regulatory affairs, possible developments in the practical uses of cloning must, of course, be taken into account. These developments must be examined in the light of wider issues of trade and social acceptability in the EU.

One regulatory option would be to live with the present EU regulation, possibly with a few amendments. This may well suffice, given the assumption that animals would only be cloned for basic research and biomedical purposes. For legislation on the uses of animals for such purposes is already in place in the EU. Against this background, the use of public resources to introduce and implement new specific regulation could be seen as wasteful. The caveat, however, would be that the cloning of animals might give rise to renewed public debate on the adequacy of the existing regulation, and on whether, for instance, that regulation provides sufficient protection for animal integrity.

The EU will be presented with greater difficulties if countries outside the EU – such as the USA, Japan, Korea and Australia – decide to allow, and perhaps even encourage, the introduction of animal cloning within agricultural production and, thus, the food chain. This is a likely development.

Even in this case, it can be argued that adequate EU regulation is in place. Existing legislation to protect consumers, human health and the environment can be applied to imports of cloned animals and products from such animals. This legislation provides for risk assessments to be carried out and acted upon, and evidence of risk is the only legitimate basis on which to restrict imports. This is a guiding principle of international trade agreements. So far, however, no risks to human health or the environment have been shown to be associated with cloned animals and their products. Thus, if the EU persists with the existing regulation alone, and if cloning techniques are applied for commercial agricultural purposes in countries outside the EU, the import of cloned animals and of products from such animals is likely to go ahead. International conflicts over free trade might be avoided. On the other hand, internal conflicts within the EU might develop, as they also might in the – at present unlikely – event that the cloning of animals is introduced into agricultural production within the EU.

Groups of citizens, and even some member states, would be likely to resist the import and/or marketing (labelled or unlabelled) of cloned animals and their products. This would prompt discussion of the question whether ethical concerns other than those relating to risk should be given regulatory force. It is possible that such ethical concerns would relate to utility, to the protection of traditional agriculture and to the integrity and naturalness of animals. Individual member states might choose to regulate, as far as possible, along such lines.

The other regulatory option is to introduce specifically targeted EU legislation on the cloning of farm animal species. This could make sense given the combined assessment (i) that the cloning in question will be used for commercial agricultural purposes, and (ii) that – although this might give rise to international trade disputes – ethical concerns other than those relating to risk should be taken into account to ensure that the application of cloning techniques is socially acceptable in a European context.

2. THE REPORT AND THE PROJECT

The main aim of this report is to present the recommendations of the project to the European Commission and other interested parties. These recommendations focus on three scenarios – or possible developments – in which cloning is applied differently. In connection with each scenario key regulatory challenges are pointed out and ethical concerns are identified.

The report draws on the six earlier reports of the project (listed below) as well as on the presentations and deliberations of the four project workshops and conferences (see below). The earlier project reports can be referred to in the course of more in-depth studies of particular aspects of the cloning technology indicated in this recommendation report. An earlier and quite different version of this report was presented and discussed at the final conference of the project in October 2006. There, European citizens from various backgrounds and countries – including high school teachers, researchers working on the project, other specialists on a range of aspects of cloning, stakeholder representatives, and representatives from the European Commission – as well as a few specialists and stakeholder representatives from the USA and Canada actively participated.

The main objectives of *Cloning in Public* were: (a) to develop recommendations on the preparation of European regulation of, and guidelines covering, research on farm animal cloning and its possible applications; and (b) to stimulate informed public debate across Europe on these issues involving key stakeholders, university students and members of the public.

It should be noted that in this report, as has been the case throughout the project, the term “cloning” refers to *asexual reproduction* – or, more precisely, to the asexual reproduction of individuals with genetic material that is virtually identical to that of the “donor” animal supplying nuclear matter. In recent debates, interest has centred on cloning by

somatic cell nuclear transfer (SCNT). The first report from the project goes into the science and technology of cloning in detail. The term “farm animal” refers to farm animal species such as ruminants (e.g. cows, sheep), pigs and poultry (e.g. chicken, turkey). The term does not necessarily imply that an animal is kept or used in an agricultural setting or for agricultural purposes. The potential application of a cloned farm animal species may therefore be in the field of biomedicine. The delimiting of the project to farm animal species leads, on the other hand, to the fact that neither triploid fish nor genetically modified mice for use in research have been examined.

Cloning in Public reports:

1. Gjerris, Mickey & Gábor Vajta (2005). *The Science and Technology of Farm Animal Cloning. A review of the state of the art of the science, the technology, the problems and the possibilities*. Danish Centre for Bioethics and Risk Assessment: Project Report 6. (This report is also published in an amended version: Gábor Vajta & Mickey Gjerris (2006). Review article: Science and technology of farm animal cloning: State of the art. *Animal Reproduction Science* 92: 211-230).
2. Meyer, Gitte (2005). *Why clone farm animals? Goals, motives, assumptions, values and concerns among European scientists working with cloning of farm animals*. Danish Centre for Bioethics and Risk Assessment: Project Report 8.
3. Lassen, Jesper (2005). *Public perceptions of farm animal cloning in Europe*. Danish Centre for Bioethics and Risk Assessment: Project Report 9.
4. Gamborg, Christian; Jennifer Gunning & Mette Hartlev (2005). *Farm Animal Cloning: The Current Legislative Framework. A review describing the existing law, and its practical application within and beyond the EU*. Danish Centre for Bioethics and Risk Assessment: Project Report 12.

5. Gunning, Jennifer; Mette Hartlev & Christian Gamborg (2006). *Challenges in regulating farm animal cloning: an assessment of regulatory approaches and the legal framework within the EU*. Danish Centre for Bioethics and Risk Assessment: Project Report 13.
6. Gjerris, Mickey (2006). *Ethics and farm animal cloning. Risks, values and conflicts*. Danish Centre for Bioethics and Risk Assessment Project Report 14.
7. Gamborg, Christian; Mickey Gjerris; Jennifer Gunning; Mette Hartlev; Gitte Meyer; Peter Sandøe & Geir Tveit (2006). *Regulating farm animal cloning. Recommendations from the project Cloning in Public*. Danish Centre for Bioethics and Risk Assessment: Project Report 15.

Cloning in Public workshops:

1. Seville 9-10 June 2005 (co-organised with EC Joint Research Centre IPTS) – an expert and stakeholder workshop designed to explore the current science, or state of the art, in cloning and possible applications of cloning technology to farm animal species.
2. Prague 24-25 November 2005 – an expert and stakeholder workshop designed to explore the ethical and regulatory aspects of research on, and uses of, cloning of farm animal species.
3. Copenhagen 23-24 September 2006 – a citizen's workshop intended to familiarise a number of European high school teachers with the key issues raised by the cloning of farm animal species in order for them to take active part in the final project conference in Brussels.
4. Brussels 5-6 October 2006 – a “participatory conference” bringing specialists, stakeholders, politicians and non-specialist citizens together to deliberate on the issues raised by the cloning of farm animal species in order to further improve the project's final recommendations to the European Commission.

Project reports, together with summaries of the workshops, can be found at the project website:
<http://www.sl.life.ku.dk/cloninginpublic.htm>

3. APPLICATIONS AND REGULATION

At EU level, animal cloning is presently governed by an indirect regulatory framework. That is, to date, the EU has passed no binding legal instruments specifically controlling animal cloning. Moving to the national level, only one of the twenty-five member states has specific legislation on the cloning of farm animals.

One of the main discussion points of the project workshop in Prague, in November 2005, was whether farm animal cloning, in plausible developmental scenarios, would be adequately regulated by present EU legislation; and if not, how it might otherwise be regulated. The question was raised again at the final project conference in Brussels, in October 2006. Here two sub-questions were identified: (1) At what level and how should the technology be regulated? (2) Upon what considerations should any regulation be based?

3.1 Possible developments and regulatory options

To ensure that the discussion is thorough, realistic and sound, a range of possible developments in the applications of cloning and several ensuing regulatory options are explored in this report. Within these scenarios, potential applications of the technology outside Europe (and in particular in the USA) are included so that trade issues are addressed.

The potential areas of application that have emerged during the project workshops and through interviews with farm animal cloning scientists can be divided in three main categories:¹

- *Basic research.* Basic research aimed at understanding embryonic development or gaining knowledge about epigenetic processes, or

laying the base on which to develop disease models.

- *Biomedicine.* Reproductive cloning as a tool for efficient production of transgenic animals that will serve mostly as disease models improving the understanding of human diseases. Such animals can also be used in the production of pharmaceuticals or, possibly, as organ donors.
- *Agriculture.* Reproductive cloning propagating a desirable genotype which could be used to reduplicate individual animals² with high genetic merit.³

The main regulatory options identified throughout the project are⁴:

- *Using existing EU regulation.* One possibility is to regulate farm animal cloning through existing regulatory mechanisms at EU level – potentially, with a few small adjustments.
- *New EU regulation.* An alternative is to introduce new regulation at EU level specifically to cover farm animal cloning.
- *National regulation.* It must be taken into account that individual member states may introduce their own national regulation independently, i.e. even if no specific regulation at EU level is introduced.

Below, three contrasting, possible combinations of the application of farm animal cloning in and outside the EU are considered in relation to the three regulatory approaches (Figure 1).

¹ These categories should not be assumed to be distinct and independent of one another.

² The prospect of mass production of animals with particularly valuable traits has been mentioned.

³ Reproductive cloning could also be used on a small scale to produce specimens of endangered species, pets or sports animals.

⁴ The three options are not mutually exclusive; different combinations of them can be imagined.

Main regulatory options	Existing regulation only	New regulation: EU level	New regulation: National level only
Possible application combinations			
Research + Medical applications in and outside the EU			
Research + Medical applications in and outside the EU + Agricultural applications outside the EU			
Research + Medical + Agricultural applications in and outside the EU			

Figure 1. The relationship between three contrasting, possible combinations of the application of farm animal cloning and the three main regulatory options can be illustrated by a matrix. This report seeks to fill in the empty spaces of the matrix.

1. In the first application combination, farm animal cloning is taken, within the EU and globally, to be used primarily for basic research purposes (e.g. to deepen understanding of basic reproduction or cell formation processes) and/or biomedical aims (the production of animals used as disease models or bioreactors). Agricultural applications – mainly in breeding and reproduction for traditional farming purposes – and other uses, such as the production of companion animals or the protection of endangered species, are assumed to be marginal.
2. In the second combination, applications in Europe are taken to be predominantly in basic research and biomedicine, but *in addition* globally (e.g. the USA, Korea, Japan, Australia), agricultural applications are assumed to play an important role.
3. It is in the third combination that the most extensive developments are envisaged. Here, agricultural applications of farm animal cloning are envisaged to be used on a large commercial scale within the EU (as well as elsewhere) along with basic research and biomedical research.

In two of the three combinations, the uses of farm animal cloning are taken to be similar within the EU and elsewhere. Apart from labelling issues,

there are no specific questions relating to trade. When it is assumed, however, that agricultural applications are used only *outside* the EU, trade-related questions become important. For example, a European ban on imports might lead to trade sanctions.

The project has identified three realistic, regulatory options that could be used to regulate the technology, each of which can be considered in connection with all three application combinations.

1. The first is to regulate farm animal cloning through existing mechanisms at EU level, potentially with some small adjustments.
2. The second is to introduce new regulation at EU level specifically to deal with farm animal cloning.
3. In the third option, individual member states are taken to introduce their own cloning regulation (i.e. national regulatory instruments that do not implement EU regulations or directives).

It should not be assumed that these three regulatory options are exclusive and exhaustive. Clearly, they could be combined in various ways. However, if for the sake of argument we treat the options as separate ones, they and the three application combinations yield nine future scenarios.

In what follows, most of these scenarios will be discussed. For each application combination, it can be discussed whether existing legislation is adequate or whether new regulatory mechanisms would be required. It can be asked what uncertainties there may be, and which steps may need to be taken. When it comes to new regulation, whether at national or EU level, many legal models and tools can be employed. Here the advantages and costs of new statutory law, administrative rules or guidelines must be analysed.

3.2. Regulatory options

In trying to come to a decision about which of the regulatory options to pursue, it is necessary to have a clear understanding of what the regulation is intended to achieve. Several factors may play a role in any decision about how to regulate.

In principle regulation could target either specific, intended applications of the technology or the

technology as such, but in practice it is difficult to pinpoint the boundaries between the two. It is often unclear what a technology might, in future, be used for at the time it is developed. This unclarity readily arises when a technique is developed in order to gain knowledge about basic biology and subsequently shows its usefulness outside the laboratory of basic research. However, it can also arise when research has a defined technological purpose. Even when a technological purpose is pre-defined, successful development of the technology often leads to an array of other uses which were not, and could not, be foreseen. Often, however, the intended development of a technology is unsuccessful. So, regulating a technology as such at an early stage of its development may lead either to restrictions on unforeseen but desirable uses of the technology, or to unnecessary legislative activity vis-à-vis a technology that will never be of any importance. If, on the other hand, the regulation targets specific intended purposes, again there will be a considerable risk of placing controls on something that will never become a practical possibility, while other unforeseen uses are left unregulated.

A number of values and concerns are at play in these decisions, including consumer protection, citizen rights, consumer choice, economic development, innovation, product safety, public health, animal welfare and animal integrity. No interpretation and assessment of the relative importance of these concerns can take place in a vacuum. Public debate will and should play an important role. As it is, public debate about biotechnology in Europe has been characterised by a divide between, on the one hand, biomedical applications of biotechnology and, on the other hand, applications relating to agriculture and food production. The former command a certain degree of acceptance whereas the latter are widely rejected. This may of course change in the light of further public debate. At the time being, the divide in public perception of biotechnology will probably affect the way in which the different concerns are interpreted, and the weight they are given in assessments of applications of farm animal cloning.

Regulatory bodies use various forms of regulation, depending on their status and powers. A statutory administrative body, such as an environmental protection agency, can create “administrative regulations” that are legally binding standards. The issuing of guidelines, recommendations or documents describing best practice is also possible. Such guidelines, of course, provide just that – guidance. As such they are not legally binding, although in practice they are often viewed as binding because they are issued by a public authority. A special licensing system can also be put into place. An example would be a system in which it is necessary to obtain a licence to clone specific animals. Systems of this kind designed to regulate animal experimentation operate in many countries. Another example is a licence allowing specific companies and research institutions to clone animals.

Where existing regulation is considered insufficient, policy makers will need to take a statutory approach. When doing so, they should consider not only the aims of future regulation but also any implications such legislation might have so far as enforcement and economic impact are concerned. In a statutory approach a range of regulatory options are available, applying to any of the scenarios:

1. The most restrictive option is to enact prohibitory legislation with penalties for failure to comply.
2. Another option is to enact detailed legislation taking account of all aspects of the technology, prohibiting certain activities and allowing others. This may give rise to hard questions about how to apply the legislation in an area where the forefront of science rapidly changes.
3. A third option is to enact framework legislation which is mainly permissive (although some activities may still be prohibited with penalties for infringement), but with regulation carried out through licensing activities by a regulatory body.

In the following, the different combinations of applications and possible regulatory approach are considered in greater detail⁵.

⁵ The content under each possible development should be seen as progressive, so that (to give an example) regulatory aspects of biomedical applications will only be stated under the first development. The report was prepared in this way in an effort to avoid needless repetition.

3.3. Possible development 1: Basic research and biomedicine applications in and outside the EU

Discussions at all the project workshops have clearly demonstrated an absence of consensus among scientists as to what applications are technically possible, economically sound and ethically acceptable. However, within biomedicine commercial applications have already emerged. In the EU several “pharming” applications are at the last stage of clinical trials and one has been approved by the EU for commercial use. Whether these applications will, in the long run, be economically feasible is still an open question. In relation to such biomedical applications, reliance could be placed on existing legislation (with some small amendments), together with existing procedures and guidelines governing the approval of pharmaceutical/medicinal products.

According to the Opinion of the Group of Advisers on Ethical Implications of Biotechnology⁶ to the European Commission – a document that has no legally binding status – the cloning of farm animal species for research is acceptable only if it is carried out under conditions which avoid or minimise animal suffering.⁷ The group supported animal cloning research on the basis that such research was likely to add to the knowledge and understanding of biological processes.

Across Europe, in EU member states, there is a raft of legislation implementing the European Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. Within the EU, any uses of farm animal cloning in basic research and biomedical research would have to comply with this legislation. Experimental animal use is, according to this legislation, acceptable, provided that alternative means of achieving the same result are duly considered, care is taken to keep the animals under good conditions, and great effort is put into designing experiments so that results can be achieved with no or minimal suffering by the animals. Typically, for each experiment a committee will have to assess whether these

conditions are fulfilled. An impact assessment of a revision of the Directive is currently (2006) ongoing. Moreover, there is specific legislation on animal experimentation in the individual countries.

The member states of the Council of Europe have agreed on a convention, with legally binding status, including a number of appendices on specific animal species.⁸ The European Convention's provisions cover areas such as care and accommodation, the conduct of experiments, humane killing, authorisation procedures, control of breeding or supplying and user establishments, education and training, and statistical information.

If farm animal cloning comes, both globally and within the EU, to be used primarily for basic research purposes (e.g. to deepen understanding of basic reproduction or cell formation processes) and/or biomedical purposes (the production of farm animals to be used as disease models or bioreactors), existing legislation would cater for an array of ethical concerns. Thus, concerns centred on risks to humans and the environment, and on the obvious welfare problems produced by research, could be taken into account. Other ethical concerns, however, such as those relating to the integrity or naturalness of animals, could not be taken into account.

3.4 Possible development 2: Basic research and biomedicine applications in and outside the EU, and agricultural applications outside the EU

It is possible that, within the EU, animal cloning techniques would be used exclusively for basic research and biomedical purposes, whereas in countries outside the EU (e.g. the USA, Korea, Japan, Australia and Canada) their employment would be extended to include commercial agricultural uses.

At the final project conference in Brussels high-ranking representatives of European farm animal breeder organisations reaffirmed that they do not

⁶ The group was succeeded in December 1997 by the “European Group on Ethics in Science and New Technologies” (EGE).

⁷ *Opinion of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission. Ethical aspects of cloning techniques*, 28 May 1997.

⁸ *European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes* (ETS No. 123), and *Protocol of Amendment to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes* (ETS No. 170).

see any use, in the foreseeable future, for farm animal cloning in breeding and reproduction. This is in line with the official policy of the umbrella body European Forum of Farm Animal Breeders (EFFAB). However, a more favourable evaluation of the future awaiting agricultural applications has been reached in the USA.

The competent authority in the USA, the Food and Drug Administration (FDA), is in the process of developing regulatory policies on meat and milk from cloned animals and their offspring. At the end of December 2006 a draft risk assessment, a proposed risk management plan, and a draft guidance for industry were issued. The main conclusions were that meat and milk from clones of adult cattle, pigs and goats, and their offspring, are as safe to eat as food from conventionally bred animals. (<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01541.html>).

In Canada regulation on animal biotechnology exists, but not a regulatory approach to cloned animals. An interim policy on foods derived from cloned animals is in use. Australia is developing a government position on the sale of non-genetically modified cloned animals as food. New Zealand does not have any particular regulation regarding animal cloning. Nor does Japan. It has been reported that Japan is now close to approving beef and milk from cloned cows and their offspring for human consumption on the basis of risk assessment studies that reportedly show these products to pose no risks to human health. Other countries may, as a result of public consultation, seek either to prohibit animal cloning or restrict it to certain applications.

Denmark is the only EU member state with legislation restricting animal cloning to research and biomedical purposes. However, so far Danish law has remained silent on the importation of cloned animals or products from such animals. The Danish act's principal aim is to protect the welfare and integrity of animals while at the same time permitting research that could have substantial benefits for human health. Norwegian law also restricts animal cloning to research purposes. In Norway, who is not an EU member, the principal aim of cloning law is to prevent

human cloning, and the law is again silent on the importation of cloned animals and products from such animals. The potential issues raised by trade, and in particular imports, if the regulation of cloning were to be secured through specifically introduced member state legislation were identified as one of the most difficult challenges at the final project conference in Brussels.

World Trade Organisation (WTO) agreements apply at both the national and the European level. Hence individual countries will probably be reluctant to enact legislation that is likely to be challenged in international courts, such as the International Court of Justice. Within both the EU and the European Economic Area (EEA) internal market provisions require the freedom of movement of goods, although within the EEA agriculture and fisheries are covered by WTO agreements only to a very limited extent. In principle, however, member states are not permitted to restrict imports of products derived from cloned animals or their offspring from fellow member states unless a risk can be scientifically demonstrated, as happened with meat products from the UK during the Bovine Spongiform Encephalopathy (BSE) outbreak.

Consequently, WTO agreements and EU legislation could conflict with national efforts to place restrictions on imports and exports of cloned animals. The question of cloning imports was discussed in the Danish Parliament when the act on animal cloning was debated. The government promised that administrative rules would be created restricting imports to cloned animals intended for use in research and requiring prior authorisation. However, so far no such rules have been introduced, and thus importation, to Denmark, of cloned animals and products from such animals is not restricted.⁹

So far as patenting is concerned, there are unresolved legal issues at both the international and EU level about the ownership and patentability of the basic process of producing cloned animals through SCNT, the patentability of the animals created thereby, and the patentability of derived products. These issues have been considered by courts, such as the European Court

⁹ In November 2006 the Danish Government took its first steps in the process of introducing import restrictions into Danish law.

of Justice, and the European Patent Office. They deserve greater public discussion. The EU Directive 98/44/EC on the legal protection of biotechnological inventions, while stating that human cloning cannot be the subject matter of a patent, is silent on animal cloning. This may seem to suggest that animal cloning is thought to be considered suitable for patenting. However, since the listing in the directive of non-patentable procedures and products is not intended to be exhaustive, it remains possible that the patenting of a cloned animal will be deemed contrary to *ordre public* and morality. In addition, the question remains whether the invention requirement governing patents is fulfilled when it comes to cloned animals.

The most pressing question within this scenario is whether a country or a region will be able either to restrict imports of cloned animals or products derived from them or their progeny, or insist on a certain kind of labelling, if the arguments are based on ethical concerns other than risks to human health or the environment. A conflict rather similar to that over genetically modified crops in the 1990s – where industry lobbied strongly against various legislative reforms, being particularly unhappy about labelling regardless of detectability – may well arise again.

3.5 Possible development 3: Basic research, biomedicine and agricultural applications in and outside the EU

Although animal cloning for general agricultural purposes does not seem likely, now or in the near future, within the EU, this development should be considered, as it may have implications for the questions whether, and if so how, to regulate.

Existing regulation

If existing regulation were relied upon, no direct action would be taken to control animal cloning as such. We would have to rely on control mechanisms already in place, and indirect regulation would be allowed to evolve by way of amendments to existing legislation (e.g. laws requiring the labelling of meat from cloned animals) and through professional codes of practice, international trade agreements and patent law, together with public pressure and market forces. This is very much the situation in the USA, where federal legislation cannot be used to prohibit an activity such as animal cloning

unless it can be shown that there is a risk to human health.

Unlike the genetic modification of animals, animal cloning is not directly regulated at EU level. However, a body of binding EU legislation, in the form of regulations and directives, addresses issues such as food safety and animal health and welfare. Additionally, zootechnical legislation regulating the trade of breeding animals might be of relevance to cloned animals used for breeding purposes, and animal identification legislation regulates the tracking of farm animals. There is also a collection of measures addressing genetically modified organisms, and these measures will apply to cloned genetically modified animals. Consumer protection is largely addressed through novel foods and labelling regulations. Nevertheless, some uncertainty and possible gaps remain in relation to farm animal cloning.

Essentially, the risk aspect of animal cloning breaks down into lower-level questions about animal health and welfare, human health, environmental effects and food safety. So far very few studies of the risks of farm animal cloning have been published. With regard to product safety issues, existing EU measures already require member states to take a number of actions to guarantee food safety and consumer choice. EU food law does not specifically address products from cloned animals or their offspring, but it includes the mechanisms to do so.

From a “consumer rights” perspective, it could be argued that there is a legal void if food products from cloned animals or their progeny are covered neither by the regulation of novel foods nor the regulation of genetically modified food.

New legislation at EU level

Under the treaty establishing the European Community, the European Commission has the “right of initiative”. This means that the Commission is responsible for drawing up new legislative proposals to put before the European Parliament and Council. On the other hand, the Commission will in general take action at EU level only if it believes that a problem cannot be addressed more effectively by national, regional or local action (the principle of subsidiarity).

The European Commission can seek to regulate by introducing binding legal instruments (regu-

lations, directives and decisions) or non-binding instruments (recommendations and opinions). In practice consensus on new EU controls on animal cloning could be difficult to achieve, as became evident at the final project conference in October 2006. Public opinion on the issue is less than clear-cut, particularly since, potentially, the technology has applications ranging from livestock improvement, providing animal models for medical research, “pharming” and the production of specialised foods such as humanised cow’s milk for infants.

National regulation in EU member states

To date only two European countries have enacted legislation on animal cloning: Denmark, an EU member state, and Norway, a member of the EEA. In other European countries the regulation of animal cloning is therefore indirect and relies on existing laws, operating at the national level, on animal protection and animal biotechnology. Institutional research ethics committees also play a non-statutory role.

3.6 Assessing regulatory options

In assessing regulatory approaches it is necessary to address the challenges that may arise from changes to the current regulatory framework. These include identifying the *aims* of further regulation (e.g. ensuring food safety) and then designing appropriate *regulatory responses*. The responses here will involve finding a suitable level of regulation (e.g. the level of EU directives), deciding upon a regulatory model (such as a rule model), and finally, determining the appropriate regulatory tool (such as binding administrative rules).

In planning regulatory apparatus for the control of farm animal cloning within the EU it is paramount to develop a common understanding of what the regulation is intended to achieve and what its underlying values are. No matter how the EU chooses to act, it will be necessary to explain the values underlying the choice.

However, it is also important, as has been argued in this report, to have a realistic view of the ways in which the technology of farm animal cloning is likely to be applied. The main uncertainty here is whether the technology will, on any considerable scale, be used within the production of meat and other animal consumables – or whether, instead, it

will only be used for basic research and biomedical purposes. Given the divide in public perceptions, in Europe at any rate, of biomedical applications of biotechnology and applications relating to agriculture and food production, it may make a significant difference which scenario turns out to be closest to actual events.

DANISH CENTRE FOR BIOETHICS AND RISK ASSESSMENT

Rolighedsvej 25

DK-1958 Frederiksberg C

www.bioethics.kvl.dk